K093271

5. 510(K) Summary or 510(K) Statement

JAN 27 2010

Submitted by: Ileana Yanes

Victus, Inc.

4918 S.W. 74 Court
Miami, FL 33155
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Date of Summary: October 13, 2009

Device Name (1) Victus Intravascular (I. V.) Administration Sets (with 0.22 μ Filter and/or Flow Regulator) and
(2) Victus I.V. Extension Sets (with 0.22 μ Filter and/or Flow Regulator)

Common Name Intravascular Administration Set

Classification Name	Regulation Number	Classification Name
	21 C.F.R §880.5440 ProCode 80 FPA	Intravascular Administration Set

Predicate Devices

Victus IV Administration Sets (K023469; K030246)
Millipore/NP Medical IVEX Filter (K832952)*
GVS SPA Flow Regulator (K061115)*
Halkey-Roberts (Robertsite Needleless Injection Site: (K002689)*

Leventon S.A. Administration Set and Extension Set with Flow Regulator with and without "Y" Connector or Needleless Access Connector (K952810)

Churchill Medical Systems Extension Set with 0.22μ & 1.2μ filter (K884370), (K894954), and (K021395), and Administration Set (K896333) and (K011336)

ICU Medical, Inc. Administration Set and Extension Set with Needle-Free straight connector and Needle-Free Injection Site (K964435) and (K970855)

Hospira, Inc. Microbore Extension Set (K052722)

McGAW, Inc. (B.Braun Medical) Administration Set (K932165)

Kendall McGAW Laboratories, Inc. Administration Set with 1.2μ filter (K896292)

AMSINO INTL., INC. Administration Set with Flow regulator (K973107)

*Note: Components manufactured by these companies will be used in the manufacture of the VICTUS I.V. Administration Sets and VICTUS I.V. Extension Sets.

Additions/ Substitution

This submission provides information on the following chances and additions to its IV Administration Set product line:

(1) substitutes a Flow Regulator (GVS SPA; K061115) for the Roller Clamp component in this system for specific applications (Note: The Roller Clamp will continue to be used in some versions of this system);

(2) replaces the PVC tubing (non DEHP) with PVC tubing (non-DEHP) in a systems; and

(3) substitutes Halkey-Roberts Needle-Free connector for the CLAVE® connector; and

(4) adds a Filter (typically 0.22μ) to some configurations of the IV Administration Set and Extension Sets; (other filter sizes such as 1.2μ may be used); and

(5) adds check valve in some configurations.

In addition, the I. V. Extension Set (with Minibore tubing with/without Filter Flow Regulator, Needle-Free straight connector and Standard (latex free) or Needle-Free Injection Site) will be marketed as an accessory for use with other I. V. Administration Sets.

None of the additions/substitutions to the device design affect safety and effectiveness of the Victus IV Administration Sets and Extension Sets.

The Victus I.V. Administration and Extension Sets are single use, sterile, non-pyrogenic devices used to administer filtered intravenous solutions and/or nutritional solution to a patient's vascular system via a catheter venous site under gravity-controlled flow. When used, the purpose of the filter is for filtering solution during intravascular administration. The device may include a needle-free valve injection site/connector which eliminates the use of needle to access the set during IV administration and aids in the prevention of needlestick injuries.

Intended Use

To administer IV fluids/medication to a patient's vascular system.

The device may include a needle-free valve injection site/connector which eliminates the use of needles to access the set during IV administration and aids in the prevention of needlestick injuries.

When included, the purpose of the filter is for filtering solution (I.V. Solution and/or Nutritional fluid) during intravascular administration.

Technological Characteristics

The IV Extension Sets & IV Sets have the same technological characteristics As the legally marketed predicate Churchill Medical Systems Extension Sets with 0.22μ and 1.2μ filter (K884370), (K894954) and Administration Set (K896333) and (K011336), Hospira, Inc. Microbore Extension Set (K052722), Leventon S.A. Administration Set and Extension Set with Flow Regulator (K952810), McGAW, Inc. Administration Set with 1.2μ filter (K932165), Kendall McGAW Laboratories, Inc. Administration Set with 1.2μ filter (K896292), ICU Medical Extension Sets with Needle-Free straight connector (K964435) and (K970855) and AMSINO INTL, Inc. Administration Set with Flow Regulator (K973107). This system incorporates PVC tubing that does not contain DEHP. The Flow Regulator that will be incorporated will be supplied by GVS SPA and is cleared under K061115.

The Technological characteristics of the Victus Sets are substantially-equivalent to the referenced predicates.

Testing

The VICTUS IV Extension Set and IV Administration Set have undergone Mechanical testing to verify performance.

Contract Manufacturer/ Sterilizer

Contract Manufacturer and Contract Sterilizer:

Plásticos y Materias Primas S.A. de C.V. (PyMPSA),

Juan de la Barrera No. 3609-2

Alamo Industrial 44700 Guadalajara, Jal. Mexico.

Establishment Registration Number: 9710643

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Ileana Yanes
Manager of Regulatory Affairs and Quality Assurance
Victus, Incorporated
4918 Southwest 74th Court
Miami, Florida 33155

JAN 27 2010

Re: K093271
Trade/Device Name: VICTUS Intravascular (IV) Administration Sets
VICTUS Intravascular (IV) Extension Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: January 19, 2010
Received: January 21, 2010

Dear Ms. Yanes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093271

Device Name: VICTUS Intravascular (IV) Administration Sets and

VICTUS Intravascular (IV) Extension Sets

Indications for Use:

To administer IV fluids/medication to a patient's vascular system.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093271